DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Public Health Service (PHS)—Food and Drug Administration (FDA)

Prerule Stage

1161. MEDICAL FOODS

Significance: Agency Priority

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 350; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360ee; 21 USC 371

CFR Citation: Not yet determined

Legal Deadline: None

Abstract: The Food and Drug Administration is considering development of regulations for medical foods, as defined by the Orphan Drug Act Amendments of 1988 (21 USC 360ee(b)(3)) to assure, among other things, the safety and effectiveness of these products, proper labeling of the nutrient content and purported uses, including adequate and appropriate directions for use, and duality control and good manufacturing practices.

Timetable:

Action	Date	FR Cite
ANPRM	11/00/93	
ANPRM Comment Period End	01/00/94	

Small Entities Affected: Businesses

Government Levels Affected: State, Federal

Agency Contact: Carol Lang, Regulatory Branch, Division of Programs and Enforcement Policy, Office of Spec Nut., Department of Health and Human Services, Public Health Service, Center for Food Safety and Applied Nutrition, (HFS-456) 200 C St. SW Washington, DC 20204, 202 205-5372

RIN: 0905–AD91

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Public Health Service (PHS)—Food and Drug Administration (FDA)

Proposed Rule Stage

1162. OVER-THE-COUNTER (OTC) DRUG REVIEW

Significance: Agency Priority

Legal Authority: 21 USC 321p; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360a; 21 USC 371a

CFR Citation: 21 CFR 310; 21 CFR 330; 21 CFR 333; 21 CFR 334; 21 CFR 335; 21 CFR 336; 21 CFR 337; 21 CFR 338; 21 CFR 339; 21 CFR 340; 21 CFR 341; 21 CFR 342; 21 CFR 343; 21 CFR 344; 21 CFR 345; ...

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. NOTE: NPRM for "Antidotes, Toxic Ingestion Products" was combined with NPRM for "Emetic Products" and reproposed as "Poison Treatment Products." NPRM for "Astringent (Wet Dressings) Products" was included in the NPRM for "Skin Protectant Products." NPRM for "Diaper Rash Products" was included in NPRMs for "Antifungal," "Antimicrobial," "External Analgesic" and "Skin Protectant Products." NPRM for "Fever Blister/Cold Sore Products (External)" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Insect Bites and Stings (Relief) Products" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." "Poison Ivy/Oak/Sumac Prevention" was included in NPRMs for "External Analgesic" and "Skin Protectant Products." NPRM for "Mercurial (Topical) Products" to be included in revised NPRM (cont)

Timetable:

Acne (Topical) Products
- ANPRM 03/23/82 (47 FR 12430)
- NPRM 01/15/85 (50 FR 2172)
- NPRM (Amendment) 08/07/91 (56 FR 37622)
- Final Action 09/16/91 (56 FR 41008)

Alcohol (Oral) in OTC Drug Products
- NPRM 11/00/93

Alcohol (Topical) Products (To be merged w/other rulemkg)
- ANPRM 05/21/82 (47 FR 22324)

Anorectal Products
- ANPRM 05/27/80 (45 FR 35576)
- NPRM 08/15/88 (53 FR 30756)
- Final Action 08/03/90 (55 FR 31776)
- Final Action (LYCD) 09/02/93 (58 FR 46746)

Antacid Drug Products
- ANPRM 04/05/73 (38 FR 8714)
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 9862)
- NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66754)
- Final Action (Amendment) (Warning) 08/26/93 (58 FR 45204)
- NPRM (Amendment) (Testing) 09/23/93 (58 FR 49826)
- NPRM (Amendment)(Sodium Bicarb.) 02/00/94

Anthelmintic Products
- ANPRM 09/09/80 (45 FR 59541)
- NPRM 08/24/82 (47 FR 37062)
- Final Action 08/01/86 (51 FR 27756)

Antibiotic First Aid Products
- ANPRM 04/01/77 (42 FR 17642)
- NPRM 07/09/82 (47 FR 29986)
- Final Action 12/11/87 (52 FR 47312)
- NPRM (Amendment) 08/18/89 (54 FR 34188)
- Final Action 03/15/90 (55 FR 9721)
- NPRM (Amendment) 05/11/90 (55 FR 19868)
- NPRM (Amendment) 06/08/90 (55 FR 23450)
- Final Action (Amendment) 10/03/90 (55 FR 40379)
- Final Action (Amendment) 12/05/90 (55 FR 50171)

Anticaries Products
- ANPRM 03/28/80 (45 FR 20666)
- NPRM 09/30/85 (50 FR 39854)
- NPRM 06/15/88 (53 FR 22430)
- Final Action 03/00/94

Antidiarrheal Products
- ANPRM 03/21/75 (40 FR 12924)
- NPRM 04/30/86 (51 FR 16138)
- Final Action 02/00/94

Antidotes, Toxic Ingestion Prdts (Now Poison Treatment Prdts)
- ANPRM 01/05/82 (47 FR 444)

Antiemetic Products
- ANPRM 03/21/75 (40 FR 12934)
- NPRM 07/13/79 (44 FR 41064)
- Final Action 04/30/87 (52 FR 15886)
- NPRM (Amendment) 08/26/93 (58 FR 45216)
- Final Action 00/00/00

Antiflatulent Drug Products
- NPRM 11/12/73 (38 FR 31260)
- Final Action 06/04/74 (39 FR 19877)
- NPRM (Amendment) 01/29/88 (53 FR 2716)

Antifungal (Topical) Products
- ANPRM 03/23/82 (47 FR 12480)
- NPRM 12/12/89 (54 FR 51136)
- NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25240)
- Final Action (Amdt.)(Diaper Rash) 12/18/92 (57 FR 60430)
- Final Action (Partial) 09/02/93 (58 FR 46744)
- Final Action 09/23/93 (58 FR 49890)

HHS—PHS—FDA

Antimicrobial Products
ANPRM 09/13/74 (39 FR 33103)
NPRM 01/06/78 (43 FR 1210)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25246)

Antiperspirant Products
ANPRM 10/10/78 (43 FR 46694)
NPRM 08/20/82 (47 FR 36492)
Final Action 00/00/00

Antiseptic First Aid
ANPRM 09/13/74 (39 FR 33103)
NPRM 01/06/78 (43 FR 1210)
NPRM (Revised) 07/22/91 (56 FR 33644)
Final Action 00/00/00

Antiseptic Products (Professional Use)
ANPRM 09/13/74 (39 FR 33103)
NPRM 01/06/78 (43 FR 1210)
NPRM (Revised) 03/00/94

Aphrodisiac Products
ANPRM 10/01/82 (47 FR 43572)
NPRM 01/15/85 (50 FR 2168)
Final Action 07/07/89 (54 FR 28780)

Aspirin (Heart Labeling)
NPRM 10/00/93

Aspirin (Reye Syndrome)
NPRM 10/00/93

Astringent (Wet Dressings) Prdts (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39436)

Benign Prostatic Hypertrophy Products
ANPRM 10/01/82 (47 FR 43566)
NPRM 02/20/87 (52 FR 5406)
Final Action 02/27/90 (55 FR 6926)

Boil Ointments
ANPRM 06/29/82 (47 FR 28306)
NPRM 01/26/88 (53 FR 2198)
Final Action 11/00/93

Camphorated Oil Drug Products
ANPRM 09/26/80 (45 FR 63869)
Final Action 09/21/82 (47 FR 41716)

Cholecystokinetic Products
ANPRM 02/12/80 (45 FR 9286)
NPRM 08/24/82 (47 FR 37068)
Final Action 06/10/83 (48 FR 27004)
NPRM (Amendment) 08/15/88 (53 FR 30786)
Final Action (Amendment) 02/28/89 (54 FR 8320)

Corn and Callus Remover Products
ANPRM 01/05/82 (47 FR 522)
NPRM 02/20/87 (52 FR 5412)
Final Action 08/14/90 (55 FR 33258)

Cough/Cold (Anticholinergic) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 07/09/82 (47 FR 30002)
Final Action 11/08/85 (50 FR 46582)

Cough/Cold (Antihistamine) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2200)
NPRM (Amendment) 08/24/87 (52 FR 31892)
Final Action 12/09/92 (57 FR 58356)

Cough/Cold (Antitussive) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/19/83 (48 FR 48576)
Final Action 08/12/87 (52 FR 30042)
NPRM (Amendment) 07/06/89 (54 FR 28442)
NPRM (Amendment) 10/02/89 (54 FR 40412)
Final Action (Amendment) 07/06/90 (55 FR 27806)
Final Action (Amendment) 10/03/90 (55 FR 40381)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27666)
NPRM (Amendment)(Ingredients) 12/09/92 (57 FR 58378)
Final Action (Warning) 10/00/93

Cough/Cold (Bronchodilator) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 10/26/82 (47 FR 47520)
Final Action 10/02/86 (51 FR 35326)
NPRM (Amendment)(Warning) 06/19/92 (57 FR 27662)
Final Action (Amendment)(Warning) 10/00/93

Cough/Cold (Combination) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 08/12/88 (53 FR 30522)
Final Action 00/00/00

Cough/Cold (Expectorant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 07/09/82 (47 FR 30002)
Final Action 02/28/89 (54 FR 8494)
Final Action (Technical Changes) 06/30/92 (57 FR 29176)

Cough/Cold (Expectorant/Ipecac) Products
Final Action 09/14/92 (57 FR 41857)

Cough/Cold (Nasal Decongestant) Products
ANPRM 09/09/76 (41 FR 38312)
NPRM 01/15/85 (50 FR 2220)
NPRM (Amendment) 06/19/92 (57 FR 27658)
Final Action 03/00/94

Dandruff, Seborrheic Dermatitis and Psoriasis Control Products
ANPRM 12/03/82 (47 FR 54646)
NPRM 07/30/86 (51 FR 27346)
Final Action 12/04/91 (56 FR 63554)
NPRM (Amendment) 04/05/93 (58 FR 17554)
Final Action (Amendment) 02/00/94

Daytime Sedatives
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 06/22/79 (44 FR 36378)

Diaper Rash Products (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39406)

Digestive Aid Products
ANPRM 01/05/82 (47 FR 454)
NPRM 01/29/88 (53 FR 2706)
Final Action 03/00/94

Emetic Products
ANPRM 03/21/75 (40 FR 12939)
NPRM 09/05/78 (43 FR 39544)

Exocrine Pancreatic Insufficiency Products
ANPRM 12/21/79 (44 FR 75666)
NPRM 11/09/85 (50 FR 46594)
NPRM (Reproposed) 07/15/91 (56 FR 32282)
Final Action 00/00/00

External Analgesic Products
ANPRM 12/04/79 (44 FR 69768)
NPRM 02/08/83 (48 FR 5852)
NPRM (Amendment) (Dandruff) 07/30/86 (51 FR 27360)
NPRM (Amendment) (Anorectal) 08/25/88 (53 FR 32592)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40818)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3370)
NPRM (Amendment) (1%Hydrocortisone) 02/27/90 (55 FR 6932)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25234)
Final Action (Diaper Rash) 12/18/92 (57 FR 60426)
Final Action 00/00/00

Fever Blister Products (Internal)
ANPRM 01/05/82 (47 FR 502)
NPRM 06/17/85 (50 FR 25156)
Final Action 06/30/92 (57 FR 29166)

Fvr Blister/Cold Sore Prdts (Ext.) (To be merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39436)

Hair Grower and Hair Loss Prevention Products
ANPRM 11/07/80 (45 FR 73955)
NPRM 01/15/85 (50 FR 2190)
Final Action 07/07/89 (54 FR 28772)

Hormone (Topical) Products
ANPRM 01/05/82 (47 FR 430)
NPRM 10/02/89 (54 FR 40618)
Final Action 09/09/93 (58 FR 57608)

Hypo/Hyperphosphatemia Products
ANPRM 12/09/80 (45 FR 81154)
NPRM 01/15/85 (50 FR 2160)
Final Action 05/11/90 (55 FR 19852)

Ingrown Toenail Relief Products
ANPRM 10/17/80 (45 FR 69128)
NPRM 09/03/82 (47 FR 39120)
Final Action 09/09/93 (58 FR 47602)

Insect Bite & Sting (Relief) Prdts (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)

Insect Repellent Drug Products (Internal)
ANPRM 01/05/82 (47 FR 424)
NPRM 06/10/83 (48 FR 26986)
Final Action 06/17/85 (50 FR 25170)

Internal Analgesic Products
ANPRM 07/08/77 (42 FR 35346)
NPRM 11/16/88 (53 FR 46204)
NPRM (Amendment) (Overindulgence) 12/24/91 (56 FR 66762)
NPRM (Amendment)((Sodium Bicarb) 02/00/94

Internal Analgesic Products (Overindulgence)
Final Action 00/00/00

Internal Deodorant Products
ANPRM 01/05/82 (47 FR 512)
NPRM 06/17/85 (50 FR 25162)
Final Action 05/11/90 (55 FR 19862)

Labeling of Drug Products for OTC Use
NPRM 04/05/93 (58 FR 17553)
Final Action 12/00/93

Laxative Products
ANPRM 03/21/75 (40 FR 12902)
NPRM 01/15/85 (50 FR 2124)
NPRM (Amendment) 10/01/86 (51 FR 35136)
NPRM (Amendment) 09/02/93 (58 FR 46589)
Final Action 00/00/00

Leg Muscle Cramps (Nocturnal Relief) Products
ANPRM 10/01/82 (47 FR 43562)
NPRM 11/08/85 (50 FR 46588)
Final Action 03/00/94

Male Genital Desensitizer Products
ANPRM 09/07/82 (47 FR 39412)
NPRM 10/02/85 (50 FR 40260)
Final Action 06/19/92 (57 FR 27654)

Menstrual Products
ANPRM 12/07/82 (47 FR 55075)
NPRM 11/16/88 (53 FR 46194)

Mercurial (Topical) Products (To be merged w/other rulemkg)
ANPRM 01/05/82 (47 FR 436)

Nailbiting/Thumbsucking Deterrent Products
ANPRM 10/17/80 (45 FR 69122)
NPRM 09/03/82 (47 FR 39096)
Final Action 09/02/93 (58 FR 46749)

Nighttime Sleep Aid Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/14/89 (54 FR 6814)
NPRM (Amendment) 08/26/93 (58 FR 45217)
Final Action 00/00/00

NDA Labeling Exclusivity
NPRM 01/00/94

Ophthalmic Products
ANPRM 05/06/80 (45 FR 30002)
NPRM 06/28/83 (48 FR 29788)
Final Action 03/04/88 (53 FR 7076)
Final Action (Anti-infective) 12/18/92 (57 FR 60416)

Oral Discomfort (Relief) Products
ANPRM 05/25/82 (47 FR 22712)
NPRM 09/24/91 (56 FR 48302)

Oral Health Care Products
ANPRM 05/25/82 (47 FR 22760)
NPRM 01/27/88 (53 FR 2436)
NPRM (Amendment) (Antimicrobials) 03/00/94
Final Action 00/00/00

Oral Mucosal Injury Products (Merged w/Oral Health Care)
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)

Oral Wound Healing Products
ANPRM 11/02/79 (44 FR 63270)
NPRM 07/26/83 (48 FR 33984)
Final Action 07/18/86 (51 FR 26112)

Otic Products (Earwax)
NPRM 07/09/82 (47 FR 30012)
Final Action 08/08/86 (51 FR 28656)

Otic Products (Swimmers Ear)
NPRM 07/30/86 (51 FR 27366)
Final Action 00/00/00

Overindulgence Remedies
ANPRM 10/01/82 (47 FR 43540)
NPRM 12/24/91 (56 FR 66742)
NPRM (Amendment)(Warning) 05/05/93 (58 FR 26686)

Overindulgence Remedies/Prevention of Inebriation
ANPRM 10/01/82 (47 FR 43540)
Final Action 07/19/83 (48 FR 32872)

Pediculicide Products
ANPRM 06/29/82 (47 FR 28312)
NPRM 04/03/89 (54 FR 13480)
Final Action 01/00/94

Poison Ivy/Oak/Sumac Prevention (Merged w/other rulemkg)
ANPRM 09/07/82 (47 FR 39412)

Poison Treatment Products
NPRM 01/15/85 (50 FR 2244)
Final Action 00/00/00

Reporting of Adverse Reactions
NPRM 12/00/93

Skin Bleaching Products
ANPRM 11/03/78 (43 FR 51546)
NPRM 09/03/82 (47 FR 39108)
NPRM (Reproposed) 03/00/94

Skin Protectant Products
ANPRM 08/04/78 (43 FR 34628)
NPRM 02/15/83 (48 FR 6820)
NPRM (Amendment) (Astringent) 04/03/89 (54 FR 13490)
NPRM (Amendment) (Poison Ivy) 10/03/89 (54 FR 40808)
NPRM (Amendment) (Fvr Blister/Ext) 01/31/90 (55 FR 3362)
NPRM (Amendment) (Diaper Rash) 06/20/90 (55 FR 25204)
Final Action (Astringent) 01/00/94
Final Action 00/00/00

Smoking Deterrent Products
ANPRM 01/05/82 (47 FR 490)
NPRM 07/03/85 (50 FR 27552)
Final Action 06/01/93 (58 FR 31236)

Sodium Labeling
NPRM 04/25/91 (56 FR 19222)
Final Action 00/00/00

Status of Certain Category II and III Ingredients
NPRM 05/16/90 (55 FR 20434)
Final Action 11/07/90 (55 FR 46914)
NPRM 08/25/92 (57 FR 38568)
Final Action 05/10/93 (58 FR 27636)

Stimulant (Overindulgence) Products
NPRM (Amendment) 12/24/91 (56 FR 66758)

Stimulant Products
ANPRM 12/08/75 (40 FR 57292)
NPRM 06/13/78 (43 FR 25544)
Final Action 02/29/88 (53 FR 6100)

Stomach Acidifier Products
ANPRM 10/19/79 (44 FR 60316)
NPRM 01/15/85 (50 FR 2184)
Final Action 08/17/88 (53 FR 31270)

Sunscreen Products
ANPRM 08/25/78 (43 FR 38206)
NPRM 05/12/93 (58 FR 28194)

Sweet Spirits of Nitre
ANPRM 02/22/80 (45 FR 11846)
Final Action 06/27/80 (45 FR 43400)

Topical Drug Products Containing Benzoyl Peroxide (Labeling)
NPRM 02/00/94

Vaginal Contraceptive Products
ANPRM 12/12/80 (45 FR 82014)
NPRM 12/00/93

Vaginal Drug Products
ANPRM 10/13/83 (48 FR 46694)
NPRM 01/00/94

Vitamin/Mineral Products
ANPRM 03/16/79 (44 FR 16126)
Withdrawal 11/27/81 (46 FR 57914)

Wart Remover Products
ANPRM 10/03/80 (45 FR 65609)
NPRM 09/03/82 (47 FR 39102)
NPRM (Amendment) 03/27/87 (52 FR 9992)
Final Action 08/14/90 (55 FR 33246)
NPRM (Amendment) (Directions) 12/00/93

Water Soluble Gums
NPRM 10/30/90 (55 FR 45782)
Final Action 08/26/93 (58 FR 45194)

Weight Control Products
ANPRM 02/26/82 (47 FR 8466)
NPRM 10/30/90 (55 FR 45788)
Final Action 08/08/91 (56 FR 37792)
NPRM (Amendment) 03/00/94

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: for "Antimicrobial Products." NPRM for "Alcohol (Topical) Products" to be included in revised NPRM for "Antimicrobial Products." The NPRM for "Antimicrobial Products" is being revised because it is being updated and split into two sections: first aid products and health care products.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Agency Contact: William E. Gilbertson, Director, Monograph Review Staff, Office of OTC Drug Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-210), 5600 Fishers Lane, Rockville, MD 20857, 301 295-8000

RIN: 0905–AA06

1163. POLICIES CONCERNING USES OF SULFITING AGENTS

Significance: Agency Priority

Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

CFR Citation: 21 CFR 182.3616; 21 CFR 182.3637; 21 CFR 182.3739; 21 CFR 182.3766; 21 CFR 182.3798; 21 CFR 182.3862; 21 CFR 100; 21 CFR 130.9

Legal Deadline: None

Abstract: Acceptable evidence and information exist to show that a subgroup of asthmatics is at moderate

to severe risk for a severe reaction upon exposure to sulfites. The agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use labeling to inform those persons who need or want to avoid the ingredient. The agency issued a final rule, effective January 7, 1987, that requires that when a sulfiting agent is present in a finished food at 10 parts per million or greater, the sulfiting agent must be declared on the label. In addition, FDA issued a final rule, effective August 8, 1986, prohibiting the use of sulfiting agents on raw fruits and vegetables intended to be served or sold raw to consumers (e.g., in salad bars). On December 10, 1987, FDA announced its tentative conclusion that there is no longer a basis to find that the use of sulfiting agents on "fresh" potatoes served or sold unpackaged to consumers is GRAS. On December 19, 1988, FDA proposed to affirm, with specific limitations, that certain other uses of sulfiting agents are GRAS (cont)

Timetable:

Food Labeling; Declaration of Sulfiting Agents
NPRM 04/03/85 (50 FR 13306)
Final Action 07/09/86 (51 FR 25012)
Effective Date 01/09/87 (51 FR 25012)
GRAS Status of the Use of Sulfiting Agents on Fresh Potatoes
NPRM-To be Merged w/Frozen Potatoes 12/10/87 (52 FR 46968)
Final Action 03/15/90 (55 FR 9826)
GRAS Status of Certain Other Food Uses of Sulfiting Agents, Etc.
NPRM 12/19/88 (53 FR 51065)
Final Action 06/00/94
Revoking Use of Sulfiting Agents on Fruits & Vegetables, Etc.
NPRM 08/14/85 (50 FR 32836)
Final Action 07/09/86 (51 FR 25021)
Final Action Effective 08/09/86 (51 FR 25021)
Status of the Use of Sulfiting Agents on Minimally Processed &
NPRM 01/00/94
Status of the Use of Sulfiting Agents on Shrimp
NPRM 12/19/88 (53 FR 51065)
Final Action 01/00/94

Small Entities Affected: None

Government Levels Affected: None

Additional Information: ABSTRACT CONT: and to establish labeling requirements for sulfiting agents in standardized foods.

On March 15, 1990 (55 FR 9826), FDA issued a final rule prohibiting the use of sulfiting agents on "fresh" potatoes (55 FR 9826) and requested data and information concerning the use of sulfiting agents on frozen potatoes (55 FR 9834).

On August 3, 1990, the United States District Court for the Middle District of Pennsylvania declared the final rule concerning fresh potatoes to be "null and void" based on perceived procedural defects in the rulemaking proceeding. The Government appealed the district court's decision. On May 22, 1991, the U.S. Court of Appeals for the Third Circuit en banc affirmed, by an equally divided vote and without opinion, the decision of the district court invalidating on procedural grounds FDA's final rule revoking the GRAS status of the use of sulfiting agents on fresh potatoes.

FDA's reproposed rule will include the GRAS status of sulfiting agents on both minimally processed (formerly fresh) and frozen potatoes.

Agency Contact: JoAnn Ziyad, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-207), 200 C Street SW., Washington, DC 20204, **202 254-9528**

RIN: 0905–AB52

1164. INFANT FORMULA ACT

Significance: Regulatory Program

Legal Authority: 21 USC 350a

CFR Citation: 21 CFR 107; 21 CFR 106

Legal Deadline: None

Abstract: The agency published on December 24, 1991, a final rule implementing the Infant Formula Act of 1986. The rule establishes infant formula record and record retention requirements. The agency is also preparing a proposed rule that will establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements and reports for the production of infant formulas.

Timetable:

Action	Date	FR Cite
Final Action	12/24/91	56 FR 66566
NPRM	03/00/94	
NPRM Comment Period End	05/00/94	

Current Good Mfg. Practices; Qual Control Proc
NPRM 10/00/93
Infant Form Cons Comp, Micro Test & Recd Retention Req
NPRM 01/26/89 (54 FR 3783)
NPRM (Comment Period End) 03/27/89 (54 FR 3783)

Small Entities Affected: None

Government Levels Affected: None

Agency Contact: Carolyn W. Miles, Nutritionist, Regulatory Branch, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-456) 200 C Street SW., Washington, DC 20204, **202 205-5372**

RIN: 0905–AC46

1165. IMPLEMENTATION OF TITLE I OF THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT

Significance: Regulatory Program

Legal Authority: 21 USC 360b

CFR Citation: 21 CFR 514

Legal Deadline: Final, Statutory, November 15, 1989.

Abstract: The agency proposes to amend its regulations to implement title I of the Generic Animal Drug and Patent Term Restoration Act which established new standards for marketing approval of generic copies of animal drug products approved after 1962.

Timetable:

Action	Date	FR Cite
NPRM	03/00/94	

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0905–AD15

1166. VOLUNTARY, FEE-FOR-SERVICE SEAFOOD INSPECTION PROGRAM

Significance: Regulatory Program

Legal Authority: 21 USC 372a

CFR Citation: 21 CFR 197

Legal Deadline: None

Abstract: The Food and Drug Administration and the National